

REMARKS/ARGUMENTS

Reconsideration of this Application is respectfully requested. Should the Examiner maintain the rejection of this application, the Applicant respectfully requests that the Examiner explicitly identify where each element as claimed is found in the references. In the Office Action of October 18, 2007, the Examiner failed to point out where each element in the independent claims was to be found in the references and failed to discuss a number of dependent claims.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited references fail to do so.

A. Claims 1-6, 10, 12-17, and 19-25 have been rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication No. 2002/0193820 to Wakuda, *et al.* (the *Wakuda* publication).

The Applicant respectfully asserts that the *Wakuda* publication fails to disclose, teach, or suggest:

a system for treating a vascular condition including a plurality of concentrically disposed restrictors circumferentially disposed on the inflatable balloon, wherein one or more restrictors are at least partially removable to allow expansion of the inflatable balloon to a predetermined size, as recited in independent claim 1;

a method of treating a vascular condition including providing a variable expansion balloon catheter including a plurality of concentrically disposed restrictors circumferentially disposed on an inflatable balloon and selecting at least one of the restrictors based on a predetermined balloon size, as recited in independent claim 12; or

a balloon catheter including a plurality of concentrically disposed restrictors circumferentially disposed on the inflatable balloon, wherein one or more restrictors are axially translatable to allow expansion of the inflatable balloon to a predetermined size, as recited in independent claim 19.

At most, the *Wakuda* publication discloses a double balloon consisting of an inner balloon 5 to be inflated by means of an introduced fluid and an outer balloon 6 for receiving the inner balloon inflated with the introduced fluid. The outer balloon 6 consists of an outer cylindrical elastic film 6a and an inner cylindrical sheath-core yarn fabric 6b for reinforcing the balloon, and the balloon-reinforcing sheath-core yarn fabric 6b is stuck to the inner surface of the elastic film 6a using a rubber cement, etc., to prevent the scattering of the elastic film 6a and to assure uniform inflation without relative shifting even if the balloon is inflated and contracted. *See* paragraphs [0041], [0042]. Nothing in the *Wakuda* publication suggests that the outer cylindrical elastic film 6a or the inner cylindrical sheath-core yarn fabric 6b restricts expansion as asserted by the Examiner. The elastic film of the inner balloon 5 is effectively reinforced by the outer balloon 6. *See* paragraph [0043]. Thus, the outer cylindrical elastic film 6a and inner cylindrical sheath-core yarn fabric 6b of the *Wakuda* publication are not restrictors as claimed.

Regarding independent claim 1, the *Wakuda* publication also fails to disclose one or more restrictors that are at least partially removable.

Regarding independent claim 12, the *Wakuda* publication also fails to disclose selecting at least one of the restrictors based on a predetermined balloon size.

Regarding independent claim 19, the *Wakuda* publication also fails to disclose one or more restrictors are axially translatable to allow expansion of the inflatable balloon to a predetermined size.

Claims 2-6 and 10, claims 13-17, and claims 20-25 depend directly or indirectly from independent claims 1, 12, and 19, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claims 2-6, 10, 13-17, and 20-25 are allowable over the *Wakuda* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding dependent claim 3, the *Wakuda* publication fails to disclose the one or more restrictors are partially removable to allow expansion of the inflatable balloon to a predetermined balloon diameter.

Regarding dependent claim 4, the *Wakuda* publication fails to disclose the one or more restrictors are partially removable to control an expandable length of the inflatable balloon.

Regarding dependent claim 5, the *Wakuda* publication fails to disclose the one or more restrictors are frictionally coupled to the inflatable balloon.

Regarding dependent claim 13, the *Wakuda* publication fails to disclose sliding the selected restrictors towards a proximal end of the variable expansion balloon catheter.

Regarding dependent claim 14, the *Wakuda* publication fails to disclose removing the selected restrictors from the variable expansion balloon catheter.

Regarding dependent claim 15, the *Wakuda* publication fails to disclose manually pulling at least one restrictor removal element attached to the selected restrictors.

Regarding dependent claim 17, the *Wakuda* publication fails to disclose controlling an expandable length of the inflatable balloon.

Regarding dependent claim 21, the *Wakuda* publication fails to disclose the one or more restrictors are axially translatable to allow expansion of the inflatable balloon to a predetermined balloon diameter.

Regarding dependent claim 22, the *Wakuda* publication fails to disclose the one or more restrictors are axially translatable to control an expandable length of the inflatable balloon

Regarding dependent claim 23, the *Wakuda* publication fails to disclose the one or more restrictors are frictionally coupled to the inflatable balloon.

Withdrawal of the rejection of claims 1-6, 10, 12-17, and 19-25 under 35 U.S.C. §102(e) as being anticipated by the *Wakuda* publication is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

B. Claims 7-9 and 26-28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Wakuda* publication in view of U.S. Patent No. 5,338,298 to McIntyre (the *McIntyre* patent).

The Applicant respectfully asserts that the *Wakuda* publication and the *McIntyre* patent, alone or in combination, fail to disclose, teach or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). As discussed in Section A above, the Applicant asserts that the *Wakuda* publication fails to disclose, teach, or suggest:

a system for treating a vascular condition including a plurality of concentrically disposed restrictors circumferentially disposed on the inflatable balloon, wherein one or more restrictors are at least partially removable to allow expansion of the inflatable balloon to a predetermined size, as recited in independent claim 1; or

a balloon catheter including a plurality of concentrically disposed restrictors circumferentially disposed on the inflatable balloon, wherein one or more restrictors are axially translatable to allow expansion of the inflatable balloon to a predetermined size, as recited in independent claim 19.

The *McIntyre* patent also fails to disclose these elements. Claims 7-9 and claims 26-28 depend directly or indirectly from independent claims 1 and 19, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claims 7-9 and 26-28 are allowable over the *Wakuda* publication in view of the *McIntyre* patent for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 7 and 26, the *McIntyre* patent fails to disclose a restrictor removal element attached to each restrictor. At most, the *McIntyre* patent discloses a cylindrical proximal collar 28 for adhesively attaching the balloon 16 to the catheter shaft 10. See Figures 1-3; column 2, lines 47-53.

Regarding claims 9 and 28, the *McIntyre* patent fails to disclose the restrictor removal element as a tab, a flap, a string, a thread, or a wire.

Withdrawal of the rejection of claims 7-9 and 26-28 under 35 U.S.C. §103(a) as being unpatentable over the *Wakuda* publication in view of the *McIntyre* patent is respectfully requested.

C. Claims 11, 18, and 29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Wakuda* publication in view of U.S. Patent No. 6,402,778 to Wang (the *Wang* patent).

The Applicant respectfully asserts that the *Wakuda* publication and the *Wang* patent, alone or in combination, fail to disclose, teach or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). As discussed in Section A above, the Applicant asserts that the *Wakuda* publication fails to disclose, teach, or suggest:

a system for treating a vascular condition including a plurality of concentrically disposed restrictors circumferentially disposed on the inflatable balloon, wherein one or more restrictors are at least partially removable to allow expansion of the inflatable balloon to a predetermined size, as recited in independent claim 1; or

a method of treating a vascular condition including providing a variable expansion balloon catheter including a plurality of concentrically disposed restrictors circumferentially disposed on an inflatable balloon and selecting at least one of the restrictors based on a predetermined balloon size, as recited in independent claim 12;

a balloon catheter including a plurality of concentrically disposed restrictors circumferentially disposed on the inflatable balloon, wherein one or more restrictors are axially translatable to allow expansion of the inflatable balloon to a predetermined size, as recited in independent claim 19.

The *Wang* patent also fails to disclose these elements. Claim 11, claim 18, and claim 29 depend directly from independent claims 1, 12, and 19, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore respectfully submits that dependent claims 11, 18, and 29 are allowable over the *Wakuda* publication in view of the *Wang* patent for at least the same reasons as set forth above for their respective independent claims.

Withdrawal of the rejection of claims 11, 18, and 29 under 35 U.S.C. §103(a) as being unpatentable over the *Wakuda* publication in view of the *Wang* patent is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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